

TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through Department of Defense and National Cancer Institute Agreement

An interagency agreement between the Department of Defense (DoD) and the National Cancer Institute (NCI) gives TRICARE* beneficiaries more options for cancer care and greater access to the latest advances in cancer prevention (including screening and early detection) and treatment through clinical trials. Known as the DoD/NCI Cancer Clinical Trials Demonstration Project, this agreement was signed in June 1999. It represents the first time that a national health plan has agreed to provide coverage for patients to participate in cancer prevention trials.

The DoD/NCI clinical trials agreement allows cancer patients who are beneficiaries of TRICARE, the medical program of the DoD, to participate in phase II and phase III NCI-sponsored cancer prevention (including screening and early detection) and treatment clinical trials and have the associated medical costs reimbursed.

Phase II clinical trials provide preliminary information about the anticancer effects of drugs or prevention agents; phase III clinical trials compare promising new cancer treatments or prevention strategies against standard care. About 20,000 cancer patients enroll in NCI treatment clinical trials each year.

*TRICARE provides medical coverage for active duty members, qualified family members, CHAMPUS-eligible retirees and their family members, and survivors of all uniformed service members.

During a cancer clinical trial, patients are cared for in the same facilities where standard care is provided. These facilities include more than 2,000 sites throughout the United States, including military hospitals, clinics, cancer centers, community hospitals, and doctors' offices. Costs for screening tests to determine clinical trial eligibility, and the associated costs of participation in cancer clinical trials are covered for qualified TRICARE members. Family members of active duty personnel, as well as TRICARE-eligible retired service members and their families, may participate in trials at military treatment facilities or in civilian health care settings. Active duty members can participate in NCI-sponsored clinical trials at military treatment facilities.

DoD's primary medical mission is to provide medical services and support to the Armed Forces during military operations, but DoD also offers health services during peacetime to members of the Armed Forces, their family members, and others entitled to DoD medical care. The DoD administers health benefits to about 8.3 million beneficiaries through its direct care system at military hospitals and clinics, as well as care purchased from civilian providers who are reimbursed by DoD.

NCI and DoD staff will evaluate the success of the demonstration project, looking specifically at actual patient enrollment and cost of care. DoD hypothesizes that the increased access to innovative cancer therapies will cost it about the same amount as it now spends on conventional care.

Questions and Answers About the DoD/NCI Clinical Trials Agreement

1. What are clinical trials?

Clinical trials are research studies conducted with people to find better ways to prevent, detect, diagnose, and treat cancer. The DoD/NCI clinical trials agreement allows TRICARE beneficiaries to participate in NCI-sponsored phase II and phase III cancer prevention and treatment trials. Under this agreement, cancer prevention clinical trials will include not only studies designed to prevent cancer but also studies to screen for cancer and to find cancer in its early stages.

2. What happens in phase II and phase III cancer prevention clinical trials covered under this agreement?

- C A **phase II** cancer prevention trial focuses on learning whether the agent being studied (medicine, vitamin, mineral, food supplement, or a combination of these) has an effect on preventing a particular type of cancer. It may also involve the use of cancer screening tests or evaluation of a method to better detect a cancer.
- C A **phase III** cancer prevention trial compares promising new agents with a standard agent or a placebo (an inactive substance that looks the same as, and is administered in the same way as, a drug in a clinical trial). Some phase III trials evaluate cancer screening tests to see if they can decrease the cancer death rate.

3. What happens in phase II and phase III cancer treatment clinical trials?

- C A **phase II** cancer treatment trial usually focuses on a particular type of cancer and provides preliminary information on the anticancer effect of a new drug or therapy.
- C A **phase III** cancer treatment trial compares a promising new treatment with standard treatment.

4. Why participate in a cancer prevention clinical trial?

Cancer prevention clinical trials are conducted with healthy people who have not previously had cancer. Prevention trials are also conducted with people who have had cancer and are trying to reduce the chance of either developing a new type of cancer or preventing a reappearance of cancer (recurrence). Prevention clinical trials are important because through research, scientists hope to determine what steps are effective in preventing cancer or finding cancer early.

There are two kinds of cancer prevention clinical trials. *Action studies* (doing something) focus on finding out whether actions people take, such as exercising more or quitting smoking, can prevent cancer. *Agent studies* (taking something) focus on examining whether taking certain medicines, vitamins, minerals, or food supplements (or a combination of them) can prevent cancer.

5. Why participate in a cancer treatment clinical trial?

Patients take part in cancer treatment clinical trials in hopes for a cure of disease, a longer time to live, or a way to feel better. Often, they feel that taking part in clinical trials benefits others by improving future cancer treatment options. Many clinical trial participants may be the first to receive new treatments before they are widely available. No cancer patient goes without treatment or receives a placebo (inactive substance) when there is a standard cancer therapy available. Cancer treatment studies lead to advances in cancer treatment, which may become the future standard care.

6. Where do patients receive care?

When participating in a DoD/NCI clinical trial, patients are closely monitored and cared for in the same facilities where standard care is provided. These facilities include more than 2,000 sites throughout the United States, such as military hospitals, clinics, cancer centers, community hospitals, and doctors' offices.

7. Who is eligible to participate in the DoD/NCI clinical trials agreement?

TRICARE beneficiaries, including retired service members and their families, and family members of active duty personnel are eligible. Medical care costs are covered when participating in both phase II and phase III NCI-sponsored clinical trials in civilian health care facilities and in military treatment facilities. Active duty members can participate in clinical trials at military treatment facilities.

8. What is covered?

Costs for screening tests to determine clinical trial eligibility, as well as the related costs of participating in the trial, are covered under this demonstration project. All usual TRICARE rules, cost shares, and deductibles apply, and eligible patients may receive care out of the TRICARE network. For more information, you may consult your health benefits advisor, or call the DoD cancer trials demonstration coordinator for your TRICARE region. For regions 6, 7, 8, 9, 10, 11, and 12, the telephone number is 1-800-395-7821. For all other regions the telephone number is 1-800-779-3060.

9. How can you learn more?

Patients and providers can learn more about patient participation in the DoD/NCI clinical trials demonstration project through the many resources listed below.

- C **Over the phone:** Call the NCI's Cancer Information Service (CIS) at 1-800-4-CANCER (1-800-422-6237), Monday through Friday, 9:00 a.m. to 4:30 p.m., local time. The CIS is a national information and education network that provides up-to-date cancer information to patients, their families, health professionals, and the general public. The CIS responds to calls in English and Spanish. Deaf and hard of hearing callers may use the toll-free TTY number at 1-800-332-8615. CIS information specialists have access to PDQ®, NCI's comprehensive computer database of cancer information, and can share information from PDQ about clinical trials covered by the demonstration project.

You may also call the DoD cancer trials demonstration project coordinator at 1-800-395-7821 if you reside in regions 6-12, or at 1-800-779-3060 if you reside in regions 1-5. Patients and health care providers can call for more information about using and authorizing this benefit, or they may contact a case manager. Pre-authorization is only required when patients are treated in a clinical trial outside of a military treatment facility.

- C **On the Internet:** The NCI has many online resources to help you locate cancer clinical trials and cancer information.

The NCI's cancerTrials™ (<http://cancertrials.nci.nih.gov>) Web site provides the latest news in cancer research and general information about clinical trials, including understanding clinical trials. You may access PDQ from this site to search for phase II and phase III cancer prevention and treatment trials covered by the DoD/NCI demonstration agreement.

CancerNet™ (<http://cancernet.nci.nih.gov>) provides up-to-date prevention, screening, treatment, and supportive care information for all types of cancer. Access to PDQ is also available from this Web site.

The DoD/NCI interagency agreement for cancer prevention and treatment clinical trials is available at <http://www.tricare.osd.mil/cancertrials/> on the Internet.

- C **PDQ/CANCERLIT® Service Center:** Health care professionals without Internet access may contact NCI's PDQ/CANCERLIT Service Center via e-mail at pdqsearch@icic.nci.nih.gov, or by telephone at 1-800-345-3300. Providing a detailed medical history will help the Service Center staff customize a clinical trials search for the patient; the searches are completed in one business day.

Patients: Talk to your doctor and discuss your choices in cancer care. Use these resources to help guide your discussion with your doctor about participating in a clinical trial.

Providers: Use these resources to help locate NCI-sponsored cancer prevention and treatment clinical trials for your patients and obtain authorization for their medical care costs.

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Sources of National Cancer Institute Information

Cancer Information Service

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY (for deaf and hard of hearing callers): 1-800-332-8615

NCI Online

Internet

Use <http://www.cancer.gov> to reach NCI's Web site.

CancerMail Service

To obtain a contents list, send e-mail to cancermail@icicc.nci.nih.gov with the word "help" in the body of the message.

CancerFax® fax on demand service

Dial 301-402-5874 and listen to recorded instructions.

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